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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,870	12/02/2003	Randall S. Hickle	82021-0033	1625
24633	7590	06/04/2009	EXAMINER	
HOGAN & HARTSON LLP IP GROUP, COLUMBIA SQUARE 555 THIRTEENTH STREET, N.W. WASHINGTON, DC 20004				NATNITHITHADHA, NAVIN
ART UNIT		PAPER NUMBER		
3735				
			NOTIFICATION DATE	DELIVERY MODE
			06/04/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/724,870	HICKLE, RANDALL S.	
	<b>Examiner</b>	<b>Art Unit</b>	
	NAVIN NATNITHITHADHA	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 March 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-15 and 32 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-15 and 32 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 02 December 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____.   | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 27 February 2009 has been entered.

### ***Response to Amendment***

2. According to the Amendment, filed 27 February 2009, the status of the claims is as follows:

Claim 1 is currently amended;

Claims 2-7, 9-12, and 14 are as originally filed;

Claims 8, 13, and 15 are previously amended;

Claim 32 is new; and

Claims 16-31 are cancelled.

### ***Response to Arguments***

3. Applicant's arguments, see Remarks, pp. 5-6, filed 29 October 2008, with respect to the rejection of claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over

Schnitzer et al, U.S. Patent No. 5,692,497 A (“Schnitzer”), in view of Derrick et al, U.S. Patent No. 5,046,491 A (“Derrick”), and further in view of Allen et al, U.S. Patent No. 6,142,950 A (“Allen”), have been fully considered, but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-15 and 32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitations “said electronic controller automatically gathers information regarding an additional aspect of the respiratory, condition of the patient when said visual display alerts the user” in claim 1, and “wherein said additional aspect of the respiratory condition comprises one of whether the patient is inhaling or exhaling, the rate of inhalation and/or exhalation, and the magnitude of inhalation and/or exhalation”,

in claim 32, are not supported by the original specification. The Applicant is urged to cite where support for the above limitations are supported in the original specification.

5. Claim 32 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the phrase "and/or" makes the claim indefinite because it is unclear as to whether the words "inhalation" and "exhalation" are included in the limitations or are alternatives.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-15 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schnitzer in view of Derrick, and further in view of Allen.

Claims 1-15: Schnitzer teaches a respiratory monitoring system 10 comprising: a patient interface (see schematic in fig. 2) comprising a "patient insert" (i.e. endotracheal tube, ETT, or reverse thrust catheter, RTC, see col. 7, ll. 35-37) 12 and a visual display 132, the nasal cannula 12 comprising at least a first nasal capnography port 19 and a first pressure sensor port 64 (see fig. 1B); a respiratory monitor (flow/pressure bi-direct alert, which detects an incorrect flow and/or an undesirable pressure) 18, comprising a pressure sensor; and an electronic controller (central processor or microprocessor 130) 22; wherein the electronic controller manages a drug delivery device, such as a

sedation and analgesia system (see col. 2, ll. 29-35, and col. 4, ll. 34-40); user interface allowing a user to enter inputs corresponding to thresholds relating to inhalation or exhalation of the patient (see col. 8, ll. 54-59; wherein pressure waveform analysis and segmentation is used to identify one of respiratory effort and effect (see col. 8, ll. 49-67); wherein alarm conditions are determined based certain criteria including relation to predetermined thresholds (see col. 9, ll. 25-36); LEDs (see col. 3, ll. 52-59); wherein the visual display 132 is updated in real time (see col. 4, ll. 24-34).

In addition, Schnitzer teach the visual display 132 alerts the user of a potential problem and the electronic controller 22 automatically gathers information regarding an additional aspect of the respiratory condition of the patient, e.g. one of whether the patient is inhaling or exhaling, the rate of inhalation and/or exhalation, and the magnitude of inhalation and/or exhalation, when said visual display alerts the user as follows (see col. 4, ll. 128-34):

The computer or microprocessor control of the invention provides flexibility so far unavailable in existing ventilators, so as to provide, for example, continuous capture of patient data for "real-time" read out or storage for future clinical or research use. The invention also provides for continuous and "real time" monitoring of relevant patient data, e.g., physiological trends, compositions, flows, pressures, volumes, and dynamic compliance data; and responds or notifies the user or connected facility of user-selected warnings, e.g., a warning buzzer, alarm or light, when a selected data characteristic is met.

In addition, Schnitzer teaches the following (see col. 8, ll. 49-67):

The feedback circuitry of the subsystem 136 with the microprocessor thus permits closed-loop control of rate, flow, oxygen concentration, circuit PEEP levels, and concentrations and flows of any other gases. These parameters are derived from the signals produced by the various sensors of FIG. 3. In the illustrated form of the invention, these signals are sampled, via the A-D converter 134, and stored in memory 135

at user-defined rates for as-needed retrieval and analysis. The memory 135 may be, for example, a floppy disk drive or internal RAM or hard drive of an associated computer. These patient data may be stored to provide a permanent log of all events related to the patient's course on the ventilator, and allow on-line and retrospective analysis of pulmonary function, i.e., compliance, and gas analysis as a function of time. Furthermore, the CPU 130 can perform operator-specific physiological calculations on-line and in real-time, such as the calculation of  $V_D/V_T$ ,  $CO_2$  production, and  $O_2$  consumption. Alternatively, these data can be stored for later analysis and review.

Thus, Schnitzer's electronic controller 22 can gather information regarding an additional aspect of the respiratory condition, e.g.  $V_D/V_T$ ,  $CO_2$  production, or  $O_2$  consumption, through "operator-specific physiological calculations on-line and in real-time".

Although Schnitzer does not explicitly teach a nasal cannula, an ear mount and a support band, Schnitzer teaches that the "subsystem 136 is connected for fluid communication with the patient 138, for example, through pneumatic tube (e.g., an ETT) and an RTC (not shown)" (see col. 7, ll. 35-37). However, Derrick teaches an apparatus for gas analysis comprising a nasal cannula 10, an ear mount/support band 28 that is adapted for placement on both ears and provides stability (see figs. 1 and 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Schnitzer to have a nasal cannula assembly because the scope of Schnitzer's invention encompasses other types of fluid communication with patients other than ETT and RTC, such as nasal cannula.

Neither Schnitzer nor Derrick teaches a visual display that "is adapted to be positioned at a suitable location on the body of a patient such that said indicators are visible to a user while simultaneously observing the patient". However, this display feature is well-known in the art. For example, Allen teaches a respiratory monitoring

system (apnea screening device) 10 comprising: a nasal interface/cannula (airflow sensor) 11 with an ear mount (adjustable elastic strap worn around the back of the head and around the ears for good stability and comfort) 20; and a display (display means) 16 (see col. 5, ll. 6-24, and col. 6, ll. 26-38). Thus, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Schnitzer in view of Derrick to have a respiratory monitoring system with a visual display adapted to be positioned at a suitable location on the body of a patient as taught by Allen in order to have a display attached to a patient that is unobtrusive, comfortable, and stable (as stated by Allen, see col. 6, ll. 26-38).

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to NAVIN NATNITHITHADHA whose telephone number is (571)272-4732. The examiner can normally be reached on Monday-Friday, 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Navin Natnithithadha/  
Examiner, Art Unit 3735  
06/01/2009